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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/298,523	04/23/1999	DAVID E. BRILES	454312-3140	2114

7590

12/04/2003

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Rochester, NY 14603

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/04/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/298,523

Applicant(s)

BRILES ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) 28-33,35-41 and 44-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-33,35-41 and 44-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of species PspC and SEQ ID NO: 13, claims 34 42 and 43, in Paper No. 28 is acknowledged. The traversal is on the ground(s) that the claimed subject matter of the different groups identified in the outstanding office action are closely related and, therefore, would require common areas of search and consideration. Applicants also argue that no benefit is derived from maintaining the restriction requirement. This is not found persuasive because the restriction Groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. For example a different sequence search is required for each individual SEQ ID NO. A reference, which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 28-33, 35-41 and 44-47 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 28.

3. Claims 34, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of immunogenic epitope or immunogenic epitopic region of PspC; where are these regions within the PspC? Claim 42 is vague and indefinite in the recitation of “an amino acid sequence of SEQ ID NO: 13”; does Applicant intend the whole of SEQ ID NO: 13 or any portion of the amino acid sequence as set forth in SEQ ID NO: 13? Claim 43 lacks positive antecedent basis in the recitation of “wherein the amino acid sequence...”.

4. It is noted that the claimed invention has an effective filing date of April 23, 1999, the filing date of the pending application 09/298523. Applicants have provided CIP applications 08/529055 and 08/714741; however the claimed invention is not disclosed in either of these applications. CIP application 08/529055, now US Patent 6592876, does not disclose PspC; this patent only discloses PspA. No amino acid sequences for PspC are disclosed. CIP application 08/714741, now US Patent 6500613, discloses PspC but does not disclose the complete amino acid sequence as set forth in SEQ ID NO: 13. The sequence search results (see attached printout) indicate only a 77% match with the claimed amino acid sequence of SEQ ID NO: 13. The results indicate that SEQ ID NO: 40 of 6500613 is a 77% match with amino acids 263-442 of SEQ ID NO: 13 and only 47% match with the complete 511 amino acid sequence of SEQ ID NO: 13. Further, it is noted that the provisional application, 60/082728, was April 23, 1998; however, this provisional application is not in sequence compliance. The effective filing date of the current application is April 23, 1999, the filing date of 09/298523. This non-provisional application fails to comply with the sequence rules. Should Applicants desire priority back to the provisional application

(60/082728), Applicants should set forth where support can be found in the provisional application for the claimed sequences.

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pages 15 [0046], 27 [0098], 38 [00125] for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 34, 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al (6573082), Wizemann et al (6503511) or Hostetter et al (6291654).

Choi et al (6573082) discloses SEQ ID NO: 13 (see SEQ ID NO: 6).

Wizemann et al (6503511) discloses SEQ ID NO: 13 (see SEQ ID NO: 6, 9 and 16).

Choi et al (6573082) discloses SEQ ID NO: 13 (see SEQ ID NO: 38 and 41).

The prior art discloses the claimed isolated polypeptide. Each reference discloses the claimed PspC from the same source as Applicants' isolated and purified polypeptide. Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

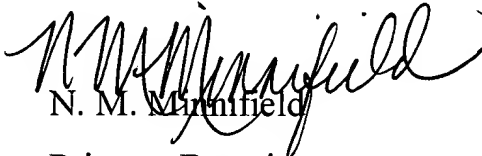
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The

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fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

December 1, 2003